IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

GAYATHRI MURTHY, Plaintiff, vs. ABBOTT LABORATORIES, Defendant.	))))))	Case No. 4:11-cv-00105-KPE JURY TRIAL DEMANDED

DECLARATION OF ANDREW P. BAUTISTA IN SUPPORT OF DEFENDANT'S REPLY BRIEF IN FURTHER SUPPORT OF MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

I, Andrew P. Bautista, declare as follows:

1. I am a partner at Kirkland & Ellis LLP ("Kirkland & Ellis"), located at 300 N. LaSalle Street, Chicago, IL 60654. Kirkland & Ellis is the counsel of record for the defendant in the above-entitled action.

2. I am a member of good standing in the State Bar of Illinois. I am authorized to appear before this Court and to make this Declaration.

3. I have personal knowledge of the matters stated herein, and if called upon, I could and would competently testify thereto.

4. Attached as Exhibit A is a true and correct copy of Plaintiffs' First Amended Complaint and Jury Demand, filed on February 9, 2010 in the matter of *Wendell v. Johnson & Johnson, et al.*, Civil Action No. 4:09-cv-04124-CW, Dkt. # 100, in the United States District Court, Northern District of California.

Executed this 23rd day of May, 2011. I declare under penalty of perjury under the laws of Texas that the foregoing is true and correct.

/s/ *Andrew P. Bautista*
Andrew P. Bautista

Exhibit A

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL & LISA WENDELL, his wife, for themselves and as successors-in-interest to MAXX WENDELL, deceased, Plaintiffs, v. JOHNSON & JOHNSON; CENTOCOR, INC; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a/ GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICAL, INC.; MYLAN LABORATORIES, INC., Defendants.	CASE NO. C 09-04124 CW **FIRST AMENDED COMPLAINT AND JURY DEMAND**

Plaintiffs STEPHEN WENDELL AND LISA WENDELL, his wife, for themselves and as successors-in-interest to MAXX WENDELL, deceased, by way of Amended Complaint against defendants say:

GENERAL ALLEGATIONS

1. This action arises from the product liability of Defendants for their drug products which plaintiff, MAXX WENDELL, deceased, consumed and thereby suffered personal injury and death. Plaintiffs STEPHEN WENDELL and LISA WENDELL, the natural parents of MAXX WENDELL, deceased, seek damages for themselves and on behalf of their son arising out of the injury and death of their MAXX WENDELL, deceased. Plaintiffs are adult persons

who are citizen of the United States and residents of Novato, California. At all times relevant hereto, the term "Plaintiffs," unless otherwise denoted, shall include MAXX WENDELL, deceased, by and through his successors-in-interest STEPHEN WENDELL and LISA WENDELL, and STEPHEN WENDELL and LISA WENDELL, his wife, for themselves.

2. MAXX WENDELL, deceased was variously prescribed Defendants' drug products Remicade® (imfliximab) and Humira® (adalimumab) in combination with Purinethol® (mercaptopurine or 6-MP) for the treatment of inflammatory bowel disease (IBD) and ulcerative colitis (UC) first diagnosed when he was 12 years old. Plaintiffs are informed and believe and thereon allege that the medications administered to MAXX WENDELL, were researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, placed in the stream of commerce, and sold or otherwise provided to Plaintiff, MAXX WENDELL, by Defendants, JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC., administered, distributed, recommended, and prescribed said medication to Plaintiff, MAXX WENDELL. This action seeks *inter alia*, general, special and punitive damages for the injuries suffered by MAXX WENDELL, deceased and his parents STEPHEN WENDELL and LISA WENDELL arising from the injuries and death of MAXX WENDELL, deceased.

3. Plaintiffs' injuries proximately resulted from the wrongful, reckless, and negligent acts and omissions, and fraudulent misrepresentations of Defendants and/or each of them, all of which occurred within the venue of this court.

4. At all times relevant to this action, the term "Defendants" includes all Defendants unless otherwise noted, including but not limited to JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC.

5. At all times relevant to this action, each of the Defendants was the officer, director, agent, servant, partner, manager, aider and abettor, employee or employer, parent or subsidiary corporation, co-conspirator and/or joint venturer of each of the other Defendants herein and were at all times operating and acting within the purpose and scope of said corporation, agency, employment, service, partnership, conspiracy and/or joint venture and ratified, condoned, and continued each others conduct and rendered substantial assistance and encouragement to the other Defendants, that their conduct constituted a breach of duty.

6. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

7. At all times herein mentioned the Defendants, and each of them were engaged in the business of or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing

and/or advertising for sale, and selling of the drugs for use and ingestion by Plaintiff, MAXX WENDELL, deceased and which actually were used and ingested by Plaintiff MAXX WENDELL.

8. At all times herein mentioned, the Defendants, and each of them, were authorized to do business within the state of California and did in fact supply, compound, distribute, formulate, prescribe and sell the aforementioned products and medications within the state of California. All of the events giving rise to this cause of action occurred in the County of San Francisco, State of California.

9. At all times herein mentioned, the officers and/or directors of the corporate Defendants named herein participated in, authorized, ratified, condoned, and directed the production and promotion of the aforementioned products and administration of medications when they knew or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs and each of them..

PLAINTIFFS

10. The events giving rise to this cause of action occurred in the County of San Francisco, State of California.

11. Plaintiffs STEPHEN and LISA WENDELL are and at all times herein were residents of the County of Marin, State of California and sue individually and as successors-in-interest, qualifying heirs and wrongful death claimants pursuant to CCP §§ 377.30 and 377.60.

12. Defendants, JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or

MYLAN LABORATORIES, INC., and each of them, failed to inform, monitor, examine, and/or warn Plaintiffs of the serious side effects associated with the use of their drugs either singly or in combination.

13. In mid-July, 2007, MAXX WENDELL, deceased, developed and was diagnosed with a rare form of cancer called hepatosplenic T-cell lymphoma. This rare cancer has been associated with the use of Defendants' products singly and/or in combination. Plaintiffs were never properly warned, properly examined or monitored by Defendants JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC. and each of them never informed Plaintiffs of the adverse side effects of the development of hepatosplenic T-cell lymphoma involved in the use of their products either singly or in combination, nor did Defendants and each of them take the proper steps to protect Plaintiff, MAXX WENDELL, from developing or preventing the further onset of hepatosplenic T-cell lymphoma, such as medical monitoring, analysis and examination, independent study, discontinuation, and administering alternative and safer treatments and medications.

14. MAXX WENDELL'S diagnosis of hepatosplenic T-cell lymphoma, from which he ultimately died, was the result of his ingestion of defective drug(s) for an extended period of time. Defendants and each of them failed to warn, monitor, examine or properly administer a safer alternative treatment, as a proximate result of which the drug(s) sold, distributed, formulated, manufactured, labeled, endorsed, and prescribed by Defendants were defective.

15. This action arises out of, *inter alia*, Defendants' willing, knowing, and intentional concealment of the serious health risks associated with the use of their drugs either singly or in

combination and Defendants' intentional failure to adequately and appropriately warn any and all persons who prescribed Defendants' product, including but not limited to any and all physicians, of the known, and/or reasonably knowable, serious and permanent risks of harm associated with the use of their drugs either singly or in combination..

DEFENDANTS

16. At all times material hereto defendant JOHNSON & JOHNSON was a corporation or other business entity with its principal place of business in the City of New Brunswick, State of Jersey and is the parent corporation of defendant CENTOCOR, a wholly-owned subsidiary of JOHNSON & JOHNSON and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical infliximab sold under the brand name Remicade®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

17. At all times material hereto, defendant CENTOCOR, INC.. was a corporation or other business entity and a wholly owned subsidiary of defendant JOHNSON & JOHNSON with its principal place of business in Malvern, Pennsylvania and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical infliximab sold under the brand name Remicade®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to

advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

18. At all times material hereto defendant ABBOTT LABORATORIES is a corporation or other business entity with its principal place of business in North Chicago, Illinois and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical adalimumab sold under the brand name Humira®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

19. At all times material hereto defendant SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE was a corporation or other business entity with its principal place of business in Philadelphia, Pennsylvania and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical mercaptopurine sold under the brand name Purinethol®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

20. At all times material hereto defendant TEVA PHARMACEUTICALS USA was a corporation or other business entity with its principal place of business in Horsham,

Pennsylvania and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical mercaptopurine sold under the brand name Purinethol®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

21. At all times material hereto defendant GATE PHARMACEUTICALS was a corporation or other business entity and a division and/or subsidiary of TEVA PHARMACEUTICALS USA with its principal place of business in Horsham, Pennsylvania and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical mercaptopurine sold under the brand name Purinethol®. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

22. At all times material hereto defendant PAR PHARMACEUTICAL, INC. was a corporation or other business entity with its principal place of business in Woodcliff Lake, New Jersey and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the

prescription pharmaceutical mercaptopurine. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

23. At all times material hereto defendant MYLAN LABORATORIES was a corporation or other business entity headquartered in Pittsburgh, Pennsylvania and was involved in the discovery and/or design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or compounding and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce the prescription pharmaceutical mercaptopurine. Said Defendant is a pharmaceutical company believed by Plaintiffs to be licensed or otherwise authorized in the State of California to advertise, sell and distribute medications to ultimate consumers like MAXX WENDELL and was and is actively engaged in such activity in and within the State of California.

24. At all times herein mentioned the Defendants, and each of them were engaged in the business of or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling their pharmaceutical products for the use and ingestion by people like MAXX WENDELL.

25. At all times herein mentioned, the Defendants and each of them, were authorized to do business within the State of California and did in fact supply and sell the aforementioned drugs within the State of California. All events giving rise to this cause of action occurred in the County of San Francisco, State of California.

26. At all times herein mentioned, the officers and/or directors of the corporate Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or with the exercise of reasonably care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the physical injuries and other damages suffered by Plaintiffs.

27. Plaintiffs allege that the corporate form of the defendant corporations, JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC. was a sham and should be disregarded because their corporate form was a mere shell, instrumentality, and conduit used as an unfair device to achieve an inequitable result and adherence to the fiction of the separate existence of the corporations would sanction a fraud or promote an injustice. Particularly, the corporate fiction has been used by the defendant corporations as a sham to perpetrate a fraud for the direct personal benefit of JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or ABBOTT LABORATORIES and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC.

28. Plaintiffs allege and will show that each of the defendant corporations was owned, managed, and operated as the alter ego of the other and each is the alter ego for the other with

respect to the ownership, management, and operation of the operations and facilities described above and the wrongful conduct which is the subject of this action. All of the wholly-owned subsidiaries were organized and operated as a mere shell, instrumentality, and conduit of the parent corporate defendant. There was such unity between the parent corporation and all of the wholly-owned subsidiaries that any individuality or separateness of the subsidiaries never existed or ceased to exist because of the unity of the interest and ownership between subsidiary and parent corporations.

29. The following facts regarding the operations of the corporate Defendants support disregard of the corporate fiction: (1) corporate formalities for all of the wholly-owned subsidiaries were ignored and were not observed; (2) property was not kept separate and apart between the parent corporation and the wholly-owned subsidiaries, which made direct deposits into bank accounts controlled by the parent corporation on a regular basis that were consolidated into the parent's deposit accounts; (3) the parent at all times maintained 100% financial interest in all subsidiaries and maintained control over the subsidiaries on an operational basis both by appointing the chief operation officer of each subsidiary and by top\down management; (4) the subsidiaries are used or established for the business purposes of the parent, and are the means by which the parent corporation conducted its business; and (5) the subsidiary facilities were not reasonably capitalized in light of the nature and risk of their business.

30. Additionally, Plaintiffs allege that at all relevant times, the defendant corporations have operated as a single business enterprise to achieve a common business purpose. Defendant parent corporations and their wholly-owned subsidiaries were not operated as separate and individual entities, but rather integrated and commingled their resources to achieve a common business purpose and conducted their operations as follows: (1) a single and common board of

directors and the same members existed between the parent and subsidiaries; (2) the same centralized and consolidated accounting and financial reporting was used by both the parent and the subsidiaries for both internal purposes and external purposes such as for the Internal Revenue Services and annual financial reports; (3) the parent corporation paid the wages of all employees, agents, and representatives of the subsidiary facilities; (4) there was a common business name used throughout the parent and subsidiaries - all subsidiaries had a version of the parent corporations name in their names; (5) there were many "corporate" departments at the subsidiary level that rendered services on behalf of the parent Corporation; and (6) the parent corporations' capital and credit lines are and were used to fund and operate the subsidiaries were solely that of the parent.

31. All of the subsidiaries of the parent corporations were established simply as shells, instrumentalities, and conduits through which the parent conducted its business, and therefore, the corporate fiction must be disregarded to prevent fraud or injustice. Each constituent corporation may be held liable for the obligations incurred by the other component entities since these Defendants operated as a single business enterprise to achieve a common business purpose.

32. The parent corporation intentionally operated all subsidiaries in a manner that left the subsidiaries without assets sufficient to satisfy the claims of the Plaintiffs, and other claimants by taking complete control and possession of the subsidiaries' revenues and receivables as soon as they were received or accrued. All monies received as proceeds in the sales of products by the subsidiary corporation were maintained and received by the parent corporation to fund its own operations and were not maintained at the subsidiary level.

FACTUAL ALLEGATIONS APPLICABLE TO ALL CAUSES OF ACTION

33. Plaintiff, MAXX WENDELL, deceased, was diagnosed with hepatosplenic T-cell lymphoma in mid-July, 2007 and died from his disease in December, 2007. From the time of his diagnosis until his death, he was required to undergo lengthy and painful examinations, treatments, testing and other diagnostic and therapeutic modalities in an ultimately unsuccessful effort to cure or alleviate his disease.

34. Plaintiffs STEPHEN and LISA WENDELL, the natural parents of MAXX WENDELL, deceased, incurred substantial economic damages in a effort to obtain a cure for their son or alleviate his suffering and otherwise sustained damages compensable under the laws of this State resulting from their son's injuries and ultimate death.

35. Plaintiffs allege that Defendants and each of them knew, or should have known, that their negligent and/or intentional, knowing, and willful failure to properly warn Plaintiffs of the adverse side effects known or knowable by Defendants to be associated with the use of their drugs singly or in combination resulted in MAXX WENDELL being exposed to a dangerous and defective product(s) which caused him seriously bodily injury from which he ultimately died.

THE DRUGS

REMICADE®

36. Remicade® is a chimeric IgG1x monoclonal antibody which neutralizes the biological activity of tumor necrosis factor alpha (TNFα) by preferentially binding with TNFα receptors thereby inhibiting TNFα from binding with its receptors. Elevated concentrations of TNFα have been found in involved tissues and fluids of patients with autoimmune disorders like rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. The drug was first approved by the federal Food and Drug Administration in 1998 for

a. in combination with methotrexate, for reducing the signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate;

b. the reduction in signs and symptoms of Crohn's disease in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; and

c. the reduction in the number of draining enterocutaneous fistulas in patients with fistualizing Crohn's disease.

37. At the time of its approval, the safety and efficacy of Remicade® in patients with juvenile rheumatoid arthritis and pediatric patients with Crohn's disease had not been established. Moreover, at the time of its approval, the safety and efficacy of Remicade® therapy for the treatment of Crohn's disease beyond a single dose had not been established nor had the safety and efficacy of Remicade® therapy in the treatment of fistualizing Crohn's disease beyond three doses been established.

38. In or about September, 2005, Remicade® received an additional indication for treatment of moderately to severely active ulcerative colitis in adults based upon a 30 week study in which the treatment group received a 5 mg/kg or 10 mg/kg dose at weeks 0, 2, 6, 14 and 22. The safety and efficacy of the drug in the treatment of of patients with juvenile rheumatoid arthritis and pediatric Crohn's disease, however, was still not established.

39. In February, 2005 Thayu, et al reported a case of hepatosplenic T-cell lymphoma in an adolescent patient after therapy with an immunomodulator (mercaptopurine) and infliximab in the Journal of Pediatric Gastroenterology.

40. In or about May, 2006, the FDA approved an additional indication for Remicade® for the treatment of active pediatric Crohn's disease based upon 54 week-long open-label clinical trial involving 112 children between the ages of 6 and 17 with moderately to severely active Crohn's disease and an inadequate response to conventional therapies. All patients in the study received doses of 5 mg/kg in weeks 0, 2 and 6. At week ten, 103 patients were randomized to a maintenance regimen of 5 mg/kg given at either 8 or 12 week intervals. For admission to this clinical trial, the patients were also required to be on a stable dose of 6-mercaptopurine, azathioprine or methotrexate. The safety or effectiveness of longer term use (> 1 year) of Remicade® for pediatric Crohn's disease nor the safety and effectiveness of the use of Remicade® use at all for the treatment of pediatric ulcerative colitis had not been established.

41. At the time of approval, the FDA also required the addition of a black box warning to the label to report six (6) post-marketing cases of hepatosplenic T-cell lymphoma in pediatric patients or young adults taking Remicade® concomitantly with either azathioprine or mercaptopurine for Crohn's disease. Exposure was between 1 or 2 infusions up to four years of treatment. Five of the six cases the patients were between the ages of 12 and 19 and four of the cases were male.

HUMIRA®

42. Humira®, like Remicade®, is a TNF blocker described as a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor. According to its label, it specifically binds to TNFα and blocks the p55 and p75 cell surface TNF receptors.

43. Humira® was approved by the FDA in 2002 for reducing signs and symptoms and inhibiting the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.

44. It was not until late February, 2007 that Humira® received an indication for the treatment of Crohn's disease. At the time of the approval of an indication for the treatment of Crohn's disease, the Dosage and Administration section of the Humira® label was amended to provide that when used for the treatment of Crohn's disease, "[a]minosalicylates, corticosteroids, and/or immunomodulatory agents (e.g. 6-mercaptopurine and azathioprine) may be continued during treatment with Humira®.

45. While the Humira® label noted that "in the controlled portions of clinical trials of all the TNF-blocking agents, more cases of lymphoma have been observed among patients receiving TNF blockers compared to control patients," and that the observed rate when the controlled and uncontrolled open-label portions of the clinical trials were combined was as much as 3.5 fold higher than expected in the general population, it also states that "rates in clinical trials for Humira® cannot be compared to rates of clinical trials of other TNF blockers and may not predict the rates observed in a broader patient population."

46. In June, 2008, the FDA issued an "Early Communication about an Ongoing Safety Review of Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Embrel, Humira, and Cimzia)." In that "Early Communication" the FDA reported that it was "investigating approximately 30 reports of cancer in children and young adults . . . [which] were submitted to FDA's Adverse Event Reporting System over a ten-year period beginning in 1998 after approval of the first TNF blocker and extending through April 29, 2008." According to the FDA, "[t]hese reports described cancer occurring in young adults who began taking TNF blockers (along with other immuno-suppressive medicines such as methotrexate, azathiopine or 6-mercaptopurine), when they were ages 18 or less, to treat Juvenile Idiopathic Arthritis (JIA), Crohn's disease or other diseases."

47. In July, 2008, Abbott Laboratories in the United Kingdom issued a "Direct Healthcare Professional Communication on reports of hepatosplenic T-cell lymphoma in patients

treated with Humira® ." In that "Direct Healthcare Professional Communication," Abbott UK reported to doctors that "[f]rom launch in December, 2002, three postmarketing reports of hepatosplenic T-cell lymphoma (HSTCL), which is a rare aggressive form of non-Hodgkin lymphoma with a poor prognosis, have been reported in patients receiving Humira® . Two of these three patients were young men also receiving azathioprine or 6-mercaptopurine for inflammatory bowel disease. A risk for the development of hepatosplenic T-cell lymphoma in patients treated with Humira® cannot be excluded. The "Direct Healthcare Professional Communication" in the United Kingdom also advised British health care providers that the labeling was being changed to add "[a] warning . . . to the product information as a risk minimization measure." That labeling change in Europe reflected the same information as contained in the Remicade black box warning in the U.S. as well as information about postmarketing reports of HSTCL associated with Humira® . The Humira® label in the United States, at least as of the time of publication of the 2009 Physician's Desk Reference does not contain any discussion like that of the Remicaid label of any association between concomitant use of TNF blockers with immunomodulator drugs and hepatosplenic T-cell lymphoma nor of the reported association between HSTCL and Humira® and, upon information and belief, Abbott Laboratories never issued a similar healthcare professional communication (known in the United States as a "Dear Doctor Letter") in the United States.

MERCAPTOPURINE (Purinethol®)

48. Mercaptopurine (also known as 6-mercaptopurine or 6-MP) is a purine analog which interferes with nucleic acid biosynthesis and has been found to be active against human leukemias. Its only FDA-approved indication is for remission induction and maintenance therapy of acute lymphatic leukemia.

49. For many years–at least since the 1990's if not earlier–mercaptopurine has been commonly used off-label in the treatment of autoimmune disorders like Crohn's disease,

inflammatory bowel disease (IBD) and rheumatoid arthritis, among others. Such use was common and known to the Defendants herein.

50. Following the approval of Remicade® in 1998 for treatment of rheumatoid arthritis and Crohn's disease in adults, it became common practice to prescribe mercaptopurine in combination concomitantly with TNF-blockers like Remicade® or Humira® in the treatment of autoimmune disorders. Such use–which was not approved by the FDA– was not only known to Defendants herein but encouraged and/or promoted and/or fostered and/or otherwise enabled by Defendants herein and each of them without adequate testing on the safety and/or efficacy of such combination use or in the pediatric or young adult populations.

MAXX WENDELL'S HISTORY

51. Maxx Wendell was born on August 20, 1986 in Arcadia, California.

52. In or about September of 1998 at the age of 12, he was diagnosed with inflammatory bowel disease (IBD) and ulcerative colitis (UC). Initially he was treated with a course of mercaptopurine (6-MP) and prednisone, a steroid.

53. In or about May, 2002 his treating gastroenterologist recommended adding Remicade® to the regimen with a course of steroid weaning.

54. In or about June or July of 2002, Maxx Wendell received his first dose of Remicade®. His treating gastroenterologist continued him on 6-MP while attempting to wean him from steroids.

55. He continued to receive Remicade® at various intervals through February, 2006, when he went into remission of his disease, all the while continuing to take 6-MP.

56. In or about November, 2006, when he experienced a relapse, his treatment regimen was modified by the inclusion of Humira® in place of Remicade®. He continued to take 6-MP as well. He received at least 5 doses of Humira® between November, 2006 and June, 2007.

57. In mid-July, 2007 Maxx Wendell was diagnosed with hepatosplenic T-cell lymphoma.

58. Despite Defendants' foregoing knowledge of the potential damage to the health and welfare of the users of their drugs when used either singly or in combination, Defendants willingly, knowingly and intentionally failed to timely and adequately warn any and all American physicians who prescribed Defendants' products, about the risk of harm associated with the use of Defendants' products when used either singly or in combination.

59. Had the labels on Defendants' products properly warned about the risk of harm associated with the foreseeable uses of Defendants' products when used either singly or in combination, MAXX WENDELL and/or his parents Plaintiffs STEPHEN and LISA WENDELL and any other reasonable persons in their position, would have been allowed the opportunity to provide their informed consent to use or not to use the product, in the manner in which it was prescribed and administered. MAXX WENDELL would not have suffered the development of hepatosplenic T-cell lymphoma and the emotional, physical and financial injuries he and his parents Plaintiffs STEPHEN WENDELL and LISA WENDELL suffered, but for the lack of proper and adequate warnings provided by Defendants in the United States.

60. Defendants, and each of them, knew, or should have known, from multiple adverse event reports and other sources that their products were unreasonably dangerous. Defendants, and each of them, failed to *inter alia* (1) provide to any and all persons who prescribed Defendants' products, including but not limited to any and all physicians, or affix to the product a proper and adequate warning of the safety risks associated with the foreseeable use of Defendants' products either singly or in combination, in particular the risk of hepatosplenic T-cell lymphoma in pediatric patients using TNF blockers in combination with immunomodulator drugs; and (2) to implement a monitoring scheme intended to identify, warn of or avoid the

adverse effects of these medications when foreseeably used singly or in combination, to the foreseeable product user.

FIRST CAUSE OF ACTION

FRAUD AND DECEIT- FRAUDULENT MISREPRESENTATION AND INTENTIONAL CONCEALMENT

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

61. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 60 as though fully set forth here and further allege as follows:

62. At all times during which Defendants, JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC. and each of them tested, produced, formulated, manufactured, sold, distributed, marketed, processed, and supplied their drug products and up to the present, Defendants, and each of them, knowingly, intentionally, willfully, and purposefully deceived Plaintiffs by (1) making false and fraudulent misrepresentations to Plaintiffs and the general public including, but not limited to, MAXX WENDELL'S treating physicians, and other American consumers of their drug products, that their drugs used either singly or in combination were safe, fit, and effective for human use; and (2) intentionally concealed from Plaintiffs and the American public and medical community, the true facts known by Defendants concerning the risks of harm associated with the use of their drugs either singly or in combination.

63. At all times relevant to this action, Defendants, JOHNSON & JOHNSON and/or CENTOCOR, INC. and/or SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE and/or

TEVA PHARMACEUTICALS USA and/or GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS, USA and/or PAR PHARMACEUTICAL, INC. and/or MYLAN LABORATORIES, INC., and each of them, knew that their representations regarding the safety and efficacy of their drug products when used either singly or in combination were in fact false and inaccurate. The true and accurate facts knowingly and intentionally concealed by Defendants, and each of them were, *inter alia*, the use of their products either singly or in combination for the treatment of various autoimmune disorders was directly associated with and/or known to cause cancers, including and particularly hepatosplenic T-cell lymphoma. This information regarding the health risks of these drugs was known or knowable by Defendants, and each of them, yet they knowingly and intentionally concealed this material information from the Plaintiffs herein, the American medical community, and other patients who were prescribed and used the drug products manufactured, produced, marketed and sold by Defendants, and each of them, either singly or in combination for the treatment of various autoimmune disorders.

64. At all times during which Defendants, and each of them, made the above mentioned fraudulent misrepresentations to and intentional concealment from Plaintiffs and MAXX WENDELL'S treating physicians, Defendants, and each of them, knew their fraudulent misrepresentations were false and inaccurate when made. Defendants, and each of them, made concealed this information and made these fraudulent misrepresentations with the specific intent to deceive Plaintiffs and induce Plaintiffs to choose their drugs over other safer alternative medical treatments for MAXX WENDELL's condition.

65. Plaintiffs would not have agreed to the use of Defendants' drug products either singly or in combination if they were aware and had been informed of the true facts and information concerning the risks of serious harm which were known or should have been known by Defendants, and each of them, to be associated with the use of their drug products, either

singly or in combination, and the causal nexus between the use of Defendants' products, either singly or in combination and the aforementioned permanent medical conditions and disorders from which Plaintiff, MAXX WENDELL ultimately suffered.

66. Plaintiffs and the prescribing treating physicians herein justifiably and reasonably relied upon the fraudulent misrepresentations and intentional concealment by Defendants, and each of them, and their agents and representatives. Plaintiffs, and their treating and prescribing doctors' reliance upon Defendants' fraudulent misrepresentations and intentional concealment was reasonable, as Plaintiffs, and these physicians did not, at all times during which plaintiff was prescribed and ingested Defendants' drug products, have the knowledge, information, or awareness of the facts regarding the adverse health effects of the use of Defendants' drug products either singly or in combination, necessary to properly evaluate whether these drugs were safe for use, either singly or in combination in the manner utilized herein.

67. At all times during which MAXX WENDELL was prescribed and ingested Defendants' drug products, Defendants, and each of them, conducted sales and marketing campaigns through Defendants' sales agents, to physicians, variously through written pamphlets, ostensible education seminars for prescribing physicians, and Defendants' internet websites to promote the sale, distribution and use of their drug products either singly or in combination in the manner and for the purpose utilized herein, with the intent to willfully and intentionally deceive Plaintiffs, MAXX WENDELL'S treating physicians, and the general consuming public as to the health risks and adverse side effects connected to the use of their drug products either singly or in combination. Defendants' fraudulent representations and intentional concealment were made directly by Defendants herein to Plaintiffs and/or MAXX WENDELL'S treating and prescribing physicians via Defendants' sales agents' written materials and brochures, internet website advertising, publications, literature, product labels, other written materials, and apparent

educational seminars regarding the use of these products either singly or in combination and in the manner utilized herein, directed to Plaintiffs and the relevant treating and prescribing physicians herein.

68. Defendants' fraudulent misrepresentations intentionally were made and conducted by Defendants' agents and representatives knowingly and willingly and with the intent to induce MAXX WENDELL and his physicians to use, consume, and ingest and prescribe for medical treatment of MAXX WENDELL's condition.

69. As a direct and proximate result of Defendants' and their agents and representatives, fraudulent and misrepresentations, intentional concealment, and deceitful conduct, Plaintiff MAXX WENDELL was prescribed and ingested Defendants' drug product(s) which caused or substantially contributed to his injuries and ultimate death.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

SECOND CAUSE OF ACTION

NEGLIGENCE, RECKLESSNESS AND GROSS NEGLIGENCE

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

70. Plaintiffs incorporate by reference and hereby realleges paragraphs 1 through 69 as though fully set forth here and further allege as follows:

71. Defendants, and each of them, as pharmaceutical manufacturers, distributors, and suppliers, had a duty to warn of adverse drug reactions of which they knew, or had reason to know or were otherwise knowable. Defendants, and all of them, knew, or should have known, the following:

a. That Defendants' drug product(s) either when used singly or in combination for the treatment of various autoimmune

disorders failed to adequately warn of the danger of cancer and in particular, hepatosplenic T-cell lymphoma;

b. That patients like MAXX WENDELL and other similarly situated users of Defendants' products used either singly or in combination were at significant risk of suffering cancer

72. In light of their knowledge of the dangers and risks associated with the use of their products and drug formulations, either singly or in combination, Defendants, and each of them, had a duty to: (a) timely and adequately warn any and all persons who prescribed Defendants' product either singly or in combination, including but not limited to, any and all physicians, of the known and/or knowable, and/or suspected risks of, *inter alia*, cancers from the use of their products when used either singly or in combination; and (b) timely implement a safer, alternative design for its products, i.e., to incorporate a warning prevention system within the product and/or to formulate a safer drug combination.

73. Defendants, and each of them, committed numerous acts of negligence in manufacturing, assembling, packaging, labeling, marketing, distributing, testing and monitoring of their drug products, including, but not limited to:

a. failing to timely and/or adequately warn any and all persons who prescribed Defendants' product, including but not limited to, any and all physicians, of the actual and known risk of harm inherent in the use of Defendants' product;

b. failing timely to implement a safer alternative product;

c. failing to conduct proper testing of their products or conduct adequate post-marketing surveillance to discover the risks associated with the use of their drugs either singly or in combination;

d. promoting use of their products in a vigorous, negligent, and fraudulent manner despite their knowledge of their products' dangerousness when used either singly or in combination, due to its failure to warn of adverse side effects.

74. As a direct, foreseeable and proximate result of the negligence of Defendants, and each of them, as hereinbefore set forth Plaintiffs suffered damages compensable under the laws of this State.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

THIRD CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

75. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 74 as though fully set forth here and further alleges as follows:

76. At all times relevant to this action, Defendants, and each of them, knew, or should have known, that their representations of the safety and efficacy of their products were in fact false and inaccurate. The true and accurate facts, falsely and negligently concealed by Defendants, were that use of Defendants' products either singly or in combination, created a serious risk of harm to patients like MAXX WENDELL. Defendants, and each of them. falsely and negligently represented that their products were safe to prescribe, use, consume and ingest, and that their product created no serious risk of harm. This falsity and inaccuracy of this information was, or should have been, known to Defendants and was negligently misrepresented to and withheld from the medical profession and the foreseeable users of their drug products.

77. At all times during which Defendants made the above mentioned misrepresentations, including but not limited to the representation that Defendants' product was safe to use, and the negligent concealment of the fact that use of Defendants' product created a serious risk of harm to patients like MAXX WENDELL, Defendants, and each of them, knew, or

should have known, and had the ability and means to ascertain, that the misrepresentations were false and inaccurate.

78. Plaintiffs had no knowledge or awareness of the falsity of Defendants' representations and believed Defendants' products to be safe for use in the manner in which they were used herein.

79. Plaintiffs reasonably relied upon Defendants' misrepresentations and were induced to and did use and agreed to be prescribed and ingest Defendants' products. Plaintiffs would not have purchased, ingested and consumed Defendants' product if they had known the true facts concerning the causal nexus between the use of Defendants' product and the aforementioned permanent injuries suffered by MAXX WENDELL.

80. Plaintiffs justifiably and reasonably relied upon Defendants' misrepresentations as Defendants were in a position of having superior knowledge regarding the safety and efficacy of their drug products, in that Defendants held themselves out to have experience and particular expertise in the field of manufacturing, testing, packaging, labeling, distributing, selling and/or prescribing medications and knew that the medical community needed and was seeking safe and effective treatments. Plaintiffs' reliance upon Defendants' misrepresentations was reasonable as Plaintiffs did not, at all times relevant to this action, have the knowledge or expertise necessary to independently evaluate whether or not the medications prescribed for MAXX WENDELL and the manner in which said medications were being administered were, in fact, safe.

81. As a foreseeable, direct and proximate result of the acts, conduct and omissions of Defendants and each of them, as hereinbefore set forth, Plaintiffs, agreed to the prescription and use Defendants' products and thereby suffered injuries compensable under the laws of this State.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

FOURTH CAUSE OF ACTION

NEGLIGENCE

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

82. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 81 as though fully set forth here and further alleges as follows:

83. At all times relevant hereto, the officers and/or directors of the corporate Defendants, and each of them named herein, participated in, authorized and/or directed the manufacture, production, packaging, labeling, distribution, promotion, sale or other placement in the stream of commerce of the aforementioned products when they knew or with the exercise of reasonably care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries sustained by Plaintiffs as hereinbefore described.

84. At all times herein mentioned, Defendants, and each of them, had a duty to exercise reasonable care in the manufacture, production, packaging, labeling, distribution, promotion, sale or other placement of their products into the stream of commerce, including a duty to assure that their drugs did not place patients at unreasonable risk of dangerous side effects, such as the development of cancer and/or that the drugs contained adequate warnings of the risks of their use. Defendants, and each of them, failed to exercise ordinary care in the manufacture, production, labeling, packaging, sale, testing, and/or distribution into interstate commerce of their products, in that Defendants, and each of them, knew or should have known that use of their drugs, either singly or in combination, presented and created a high risk of unreasonable and serious, dangerous side effects, some of which were irreversible and potentially fatal, such as cancer.

85. Defendants, and each of them, negligently and carelessly manufactured, designed, formulated, compounded, tested, produced, processed, assembled, inspected, researched, distributed, marketed, labeled, packaged, prepared for use, sold and failed to adequately test, research and warn any and all persons who prescribed Defendants' product, including but not limited to, any and all physicians and their patients, of the risks and dangers of the use of Defendants' products either singly or in combination. This negligence and carelessness involves, *inter alia*:

a. Failure to use due care in manufacturing these pharmaceutical agents so as to avoid the aforementioned risks to individuals when these agents were being prescribed, sold, consumed, ingested and used;

b. Failure to accompany their products with proper warnings regarding all possible adverse side effects associated with use, consumption, and ingestion of this pharmaceutical agents and the comparative severity and duration of such adverse effects; the warnings given, if any, did not accurately and truthfully reflect the risks of developing or the symptoms, scope or severity of side effects;

c. Failure to conduct adequate and sufficient pre clinical and clinical testing and/or post-market surveillance to determine the safety and efficacy of their drug products as used;

d. Failure to provide adequate training to medical care providers for the appropriate use and prescribing of their drugs;

e. Failure otherwise to exercise due care under the circumstances or act as a reasonable product manufacturer and in particular a pharmaceutical manufacturer would under the circumstances.

86. Defendants, and each of them, knew or should have known that consumers and patients such as Plaintiffs herein foreseeably would suffer serious harm and injury as a result of the failure of Defendants, and each of them, to exercise ordinary care as hereinbefore set forth.

87. As a foreseeable, direct, proximate and legal result of the negligence, carelessness, and other wrongdoing or tortious actions or inactions of Defendants, and each of them, Plaintiff MAXX WENDELL sustained permanent and devastating physical injuries, from which he ultimately died. These injuries caused extensive pain, suffering and emotional distress not only to MAXX WENDELL but his parents who were also caused to expend substantial sums of money for medical, hospital, and related care in an unsuccessful effort to cure or alleviate their son's disease and suffering. Plaintiffs also sustained general and other damages compensable under the laws of this State.

88. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, as described herein, Plaintiff MAXX WENDELL, was injured in his health, strength, and activity and suffered serious injuries to his body and mind, including death. All of said injuries caused MAXX WENDELL and his parents intense anxiety, distress, fear, pain, suffering and distress secondary to his permanent injury and damages. These injuries have generally damaged Plaintiffs in a sum above the court's jurisdictional minimum.

89. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, MAXX WENDELL sustained loss of earnings and earning capacity in the future. The exact amount is presently unknown to Plaintiffs at this time.

90. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, MAXX WENDELL required reasonable and necessary health care, attention and services and he and/or his parents, Plaintiffs STEPHEN and LISA WENDELL did incur medical, incidental and service expenses thereupon for which they seek recovery.

91. The conduct of Defendants, and each of them, in formulating, licensing, manufacturing, assembling, packaging, labeling, warning, marketing, advertising, promotion, distribution, and sale of the products, included but is not limited to:

a. Marketing and aggressively promoting their products for non-indicated uses in non-indicated fashions and in non-indicated patient groups, either knowing the high risks posed by such use or failing to know such risks because of their failure to conduct sufficient pre-clinical or clinical testing or perform adequate post marketing surveillance;

b. Failing to provide complete truthful, and accurate warnings,literature, instructions, or training to health care professionals indicating the proper use of their products either singly or in combination;

c. Failing to provide and include adequate warnings with their products being used either singly or in combination that would alert physicians and their patients of the potential risks and the nature, scope, severity and duration of any serious side effects of their drugs either when used singly or in combination, particularly, the risk of permanent and potentially fatal cancers;

d. Continuing to promote the efficacy or safety of their drugs for use either singly or individually while providing no warning or inadequate warnings, thus downplaying the risks, even after Defendants, and each of them, knew of the risks, including development of cancers;

e. Delaying warnings of, and then failing to provide adequate, accurate, and truthful warnings about permanent cancers arising from the use of their drugs, either singly or in combination, which may have dissuaded medical providers from prescribing the drugs so freely and depriving medical providers of the ability to understand and measure the true risks against the benefits of prescribing these medications either singly or in combination in the manner and for the purposes as herein, was fraudulent, conscious, knowing misconduct, intended to insure that Defendants, and each of them, continued to enjoy the large profits Defendants, realized from the sales of their drugs from the manner in and use to which the drugs were put, which profits Defendants, and each of them, knew would cease if Defendants, and each of them, warned or otherwise

> adequately informed doctors and their patients of the dangers of their drugs when used either singly or in combination in the manner in and use to which the drugs were put.

92. The conduct of Defendants, and each of them, was undertaken recklessly and with conscious disregard for the safety of consumers such as Plaintiff, MAXX WENDELL, such as to constitute despicable conduct, oppression, fraud and malice, and such conduct was at all times relevantly ratified by the corporate Defendants, and each of them,thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish and make an example of Defendants.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages, including punitive damages, plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

FIFTH CAUSE OF ACTION

NEGLIGENCE *PER SE*

(AGAINST ALL DEFENDANTSEXCEPT ABBOTT LABORATORIES)

93. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 92 as though fully set forth here and further allege as follows:

94. Defendants, and each of them, have an obligation to not violate the law in their acts and conduct.

95. Defendants, and each of them, have violated the California Consumer Protection Statutes and all related and other laws, statues, and regulations applicable to Defendants' wrongful conduct.

96. Plaintiffs as patients and/or purchasers and/or consumers of the drugs at issue herein are within the class of persons the statutes described above are designed to protect. Injury suffered as a result of and due to false advertising, misbranding, misleading labeling or

warnings, and promotion of unsafe products is the type of harm the above-cited statutes are designed to prevent.

97. Defendants, and each of them, are directly responsible to Plaintiffs for Defendants' violations of the statutes described above under the doctrine of negligence *per se*.

98. As a direct and legal result of the violations of the statutes described above, Plaintiff MAXX WENDELL, suffered suffer serious injury and harm, ultimately resulting in his death, and Plaintiffs have otherwise suffered economic loss, as alleged in this complaint and otherwise sustained damages compensable under the laws of this State.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

SIXTH CAUSE OF ACTION

STRICT LIABILITY IN TORT – FAILURE TO WARN

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

99. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 98 as though fully set forth here and further allege as follows:

100. Defendants, and each of them, are the designers, manufacturers, testers, researchers, developers, compounders, packagers, labelers, distributors, suppliers and/or sellers of the pharmaceutical drug products hereinbefore set forth and/or were otherwise responsible for placing those drugs into the stream of commerce.

101. The drugs designed, manufactured, tested, researched, developed, compounded, packaged, labeled, distributed, supplied and/or sold by Defendants, and each of them, were and are unaccompanied by proper and adequate warnings regarding their risks, including possible cancers, among others, associated with the use of their drugs either singly or in combination and

the comparative severity and duration of the injuries which could result from such risks; the warnings given did not accurately, truthfully, or adequately reflect the risks or the symptoms, scope, and severity of the injuries which could result from such risks.

102. Defendants, and each of them, failed to perform adequate pre-market or post-market testing of their drugs and their use by patients in the manner and for the purposes they were used herein which testing would have shown that the use of these drugs either singly or in combination posed significant risks, including but not limited to, development of serious and potentially fatal cancers. Defendants, and each of them, also failed to conduct proper post-market surveillance to determine the manner in and purposes for which their drugs were being used and the risks of such use. Defendants, and each of them, upon placing their products into the stream of commerce, had a duty to fully understand the risks posed by their drug products and to fully and properly warn of the risks posed by their drugs, which warnings were required to accurately and fully warn of the symptoms, scope, and severity of the risk and potential injuries associated with the use of their drugs either singly or in combination.

103. Defendants, and each of them, knew or should have known their products used, either singly or in combination, were and are dangerously defective products which pose unacceptable risks unknown and unknowable by the consuming public, including Plaintiffs.

104. Defendants, and each of them, not only failed to adequately warn the foreseeable users of their products but also failed to adequately warn any and all persons who prescribed Defendants' products, including but not limited to, any and all physicians, of the risks posed bythat the use of their drugs, either singly or in combination.

105. The drug products manufactured and/or supplied by Defendants, and each them, were defective due to false and inadequate warnings because, after the manufacturers knew or should have known of risks, from their use either singly or in combination, they failed to provide

adequate warnings to prescribers of the product or patients and continued to aggressively market, promote, distribute, and sell these dangerously defective products.

106. As a foreseeable, direct, proximate and legal result of the negligence, carelessness, and other wrongdoing or tortious actions or inactions of Defendants, and each of them, Plaintiff MAXX WENDELL sustained permanent and devastating physical injuries, from which he ultimately died. These injuries caused extensive pain, suffering and emotional distress not only to MAXX WENDELL but his parents who were also caused to expend substantial sums of money for medical, hospital, and related care in an unsuccessful effort to cure or alleviate their son's disease and suffering. Plaintiffs also sustained general and other damages compensable under the laws of this State.

107. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, as described herein, Plaintiff MAXX WENDELL, was injured in his health, strength, and activity and suffered serious injuries to his body and mind, including death. All of said injuries caused MAXX WENDELL and his parents intense anxiety, distress, fear, pain, suffering and distress secondary to his permanent injury and damages. These injuries have generally damaged Plaintiffs in a sum above the court's jurisdictional minimum.

108. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, MAXX WENDELL sustained loss of earnings and earning capacity in the future. The exact amount is presently unknown to Plaintiffs at this time.

109. As a foreseeable, direct, proximate and legal result of the negligence, carelessness and other wrongdoing and tortious actions or inactions of Defendants, and each of them, MAXX WENDELL required reasonable and necessary health care, attention and services and he and/or

his parents, Plaintiffs STEPHEN and LISA WENDELL did incur medical, incidental and service expenses thereupon for which they seek recovery.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

110. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 109 as though fully set forth here and further allege as follows:

111. At all times relevant hereto, Defendants, and each of them, expressly warranted by way of written literature, including, but not limited to product labeling, patient package inserts, articles in medical journals, advertising or other documents and/or promotional materials directed to Plaintiffs' physicians and/or Plaintiffs, by and through statements made by Defendants, and each of them, or their authorized agents or sales representative, orally and/or in publications package insert, or other written materials intended for physicians and/or their patients, that the aforementioned products were safe, effective, fit and proper for their intended use, through the course of that use by MAXX WENDELL and/or others similarly situated and/or the general public to whom it was prescribed, supplied or dispensed.

112. Plaintiffs were prescribed and/or purchased and/or consumed and/or otherwise ingested the Defendants' drug products. In so doing, Plaintiffs relied upon the skill, judgment, representation and the foregoing express written warranties of the Defendants and each of them. Said warranties and representations were false, misleading and inaccurate in that the aforementioned products were not safe and were unfit for the uses for which they were intended

or put with the knowledge and/or encouragement and/or approval of Defendants and each of them.

113. As a result of the breaches of express warranties by the Defendants, and each of them, as hereinbefore set forth, Plaintiffs, after purchasing and/or consuming and/or ingesting Defendants' subject drugs, suffered injuries and damages compensable under the laws of this State as set forth herein.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

114. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 113 as though fully set forth here and further allege as follows:

115. Prior to the time that the aforementioned products were used by Plaintiff, MAXX WENDELL, Defendants, and each of them, impliedly warranted to Plaintiffs and/or Plaintiff's physicians that said products were of merchantable quality and safe and fit for the use for which they were intended or other known or foreseeable uses.

116. Plaintiffs were and are unskilled in the research, design, and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranties of the Defendants, and each of them, in being prescribed, purchasing, consuming and ingesting the aforementioned products.

117. The aforementioned products were neither safe for their intended, known or foreseeable uses nor of merchantable quality, as warranted by Defendants, and each of them, in

that they had the potential for permanent injuries when put to their intended, known or foreseeable uses and would cause such injuries to the foreseeable users of their products.

118. As a result of the aforementioned breaches of the implied warranties by the Defendants, and each of them, Plaintiffs, after being prescribed and/or after purchasing and/or consuming and/or ingesting defendant's products suffered injuries and damages compensable under the laws of this State as alleged herein.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

NINTH CAUSE OF ACTION

VIOLATION OF BUSINESS AND PROFESSIONS CODE SECTION 17200, ET SEQ.

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

119. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 118 as though fully set forth here and further allege as follows:

120. Plaintiffs bring this cause of action pursuant to California *Business & Professions Code* Section 17200, et seq., for themselves, and not on behalf of the general public.

121. California *Business & Professions Code* Section 17200 provides that unfair competition shall mean and include "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."

122. At all times herein, Defendants, and each of them, engaged in a pattern of practice of advertising and marketing of their drug products as safe and effective medications, even though Defendants, and each of them, knew or should have known that the foreseeable use of the products either singly or in combination could cause serious adverse health effects. The acts and practices of Defendants, and each of them, as described in this complaint constitute unlawful, unfair and fraudulent business acts or practices and were and are likely to mislead the Plaintiffs

and, therefore, constitute unfair business practices within the meaning of *Business & Professions Code* Sections 17200 *et seq.* The conduct of Defendants, and each of them involving untrue and misleading advertising as set forth in this complaint are incorporated by reference into this cause of action and constitute violations of *Business & Professions Code* Sections 17200, *et seq.* This conduct includes, but is not limited to:

a. Representing to Plaintiffs, and the general public, that said products and their use were safe, fit, and effective for human consumption, knowing that said representations were false, and concealing from Plaintiffs, and the general public, that said products had a serious propensity to cause injuries to foreseeable users;

b. Purposely and affirmatively downplaying and understating the health hazards and risks known by Defendants, and each of them, to be associated with the foreseeable uses of their drugs either singly or in combination

c. Issuing promotional literature which deceived potential users of their drug products by relaying positive information regarding the medication and manipulating information to indicate widespread acceptance of the products and medications among patients like MAXX WENDELL, while downplaying the adverse, serious and permanent health effects known or knowable by Defendants, and each of them, and concealing material relevant information regarding the safety and efficacy of the products when put to their intended or foreseeable uses.

123. These practices by Defendants, and each of them, constitute unlawful, unfair and fraudulent business acts or practices within the meaning of California *Business & Professions Code* Sections 17200, *et seq.*, as well as unfair, deceptive, untrue, and misleading advertising also prohibited by California *Business & Professions Code* Sections 17200, *et seq.*

124. The unlawful, unfair and fraudulent business practices of Defendants, and each of them, as described herein present a potential continuing threat to members of the public to the extent that Defendants continue to engage in the conduct described herein.

125. As a result of their conduct described above, Defendants, and each of them, have been and will continue to be unjustly enriched. Specifically, Defendants, and each of them, have been unjustly enriched by receipt of ill gotten gains from the prescription and sale said products in California and throughout the United States, which sales occurred primarily as a result of the acts and omissions of Defendants, and each of them, as described herein.

126. Because of the fraudulent misrepresentations made by Defendants, and each of them, as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information concerning the safety and efficacy of prescription medications, the acts of Defendants, and each of them, described herein constitute unfair or fraudulent business acts or practices.

127. Pursuant to California *Business & Professions Code* section 17203, Plaintiffs seek an Order from this court to provide restitution and to disgorge the monies collected and profits realized by Defendants, and each of them, as a result of their unfair business acts and practices and injunctive relief calling for Defendants, and each of them to immediately and forever cease such unfair business practices.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

TENTH CAUSE OF ACTION

WRONGFUL DEATH

(AGAINST ALL DEFENDANTS EXCEPT ABBOTT LABORATORIES)

128. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 127 as though fully set forth here and further allege as follows:

129. As a foreseeable, direct and proximate result of the negligent, tortious or otherwise wrongful conduct of Defendants, and each of them, as hereinbefore set forth, plaintiff MAXX WENDELL developed an aggressive and deadly form of cancer to which he ultimately succumbed.

130. The death of plaintiff MAXX WENDELL was a foreseeable, direct and proximate result of the negligent, tortious or otherwise wrongful conduct of Defendants, and each of them, as hereinbefore set forth.

WHEREFORE, plaintiffs demand judgment against defendants individually, jointly, severally and in the alternative for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

ELEVENTH CAUSE OF ACTION

NEGLIGENCE

(AGAINST ABBOTT LABORATORIES)

131. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 130 as though fully set forth here and further allege as follows:

132. At all times material hereto, defendant Abbott Laboratories had a duty to warn of known or knowable risks associated with foreseeable uses of its drug products, including Humira®. Regardless of FDA approval of a drug's label, it is the manufacturer which bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

133. At the times and places aforesaid and at all times material hereto, the risk of hepatosplenic T-cell lymphoma arising from the use of Humira® either singly or in combination with immunomodulator drugs was either known to defendant Abbott Laboratories or was scientifically knowable based upon adequate clinical testing or proper post-marketing

surveillance including reviews of published medical literature and/or monitoring of spontaneous adverse event reports or other post-marketing surveillance designed to discover serious adverse events associated with the foreseeable use of Humira®.

134. At the times and places aforesaid and at all times material hereto, defendant Abbott Laboratories failed to adequately warn prescribing physicians—who in turn could warn patients—about the known or knowable risks of the foreseeable uses of Humira® when used either singly or in combination with immunomodulating drugs like 6-MP. Specifically, at no time during the times relevant to this action did defendant Abbott Laboratories advise prescribing physicians or the general public in the United States about the known or knowable risk of hepatosplenic T-cell lymphoma in pediatric patients using Humira® concomitantly with immunomodulating drugs like 6-MP even though defendant was aware of such use of its drug and was aware that its competitor in the marketplace did provide information to physicians about the association between use of Remicade in combination with immunomodulating drugs and hepatosplenic T-cell lymphoma in pediatric patients.

135. The failure to provide information on the Humira® label similar to that provided in the Remicade label was intended to gain and maintain a competitive advantage in the marketplace by implying that Humira® did not carry the same risks as other drugs of the same class.

136. Defendant Abbott Laboratories knew, or should have known in the exercise of reasonable care that its drug carried the same or similar risk of hepatosplenic T-cell lymphoma as other TNF-blocking drugs particularly when used in combination with immunomodulating drugs like 6-MP but negligently failed to discover this risk and/or negligently failed to provide an adequate warning about such risk.

137. As a foreseeable, direct and proximate result of defendant Abbott Laboratories' negligence as hereinbefore set forth, plaintiffs' physicians were not adequately warned of the risks of defendants drugs and were therefore not "learned" intermediaries for the purposes of informing their patients of the risks and benefits of drugs which they recommended for use.

138. As a foreseeable, direct and proximate result of defendant's negligence in failing to provide an adequate warning about the risks of its drug when used in foreseeable ways and in foreseeable populations, defendants' drug was defective and this defect proximately caused plaintiffs' injuries, including the death of MAXX WENDELL.

WHEREFORE, plaintiffs demand judgment against defendant Abbott Laboratories for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

TWELFTH COUNT

STRICT LIABILITY

(AGAINST ABBOTT LABORATORIES ONLY)

139. Plaintiffs incorporate by reference and hereby re-allege paragraphs 1 through 138 as though fully set forth here and further allege as follows:

140. At the times and places aforesaid and at all times material hereto, defendant Abbott Laboratories was a pharmaceutical company engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise involved in placing into the stream of commerce various drug products, including the drug Humira® intended for human use, ingestion and consumption.

141. At the times and places aforesaid and at all times material hereto, defendant Abbott Laboratories held itself out as knowledgeable and possessing the requisite skill particular to the

development and/or research and/or manufacture and/or production and/or testing and/or assembling and/or packaging and/or distribution and/or sale of such products, including Humira®.

142. Because defendant Abbott Laboratories' drug Humira® was not accompanied by an adequate warning on its label providing sufficient information to physicians and patients about the known or knowable risks of Humira® when used either singly or in combination with immunomodulating drugs like 6-MP, as hereinbefore set forth, the product was unreasonably dangerous and in a defective condition.

143. At the times and places aforesaid and at all times material hereto, defendant Abbott Laboratories placed or caused to be placed into the stream of commerce a drug product which was unreasonably dangerous and in a defective condition and is strictly liable in tort for injuries suffered from the use, consumption or ingestion of its defective product.

144. As a direct, foreseeable and proximate result of the placement of a defective product into the stream of commerce by Abbott Laboratories, as hereinbefore set forth, MAXX WENDELL suffered serious bodily injuries, from which he ultimately died, and plaintiffs otherwise suffered damages compensable under the laws of the State of California and/or the United States.

WHEREFORE, plaintiffs demand judgment against defendant Abbott Laboratories for damages plus interest, attorney's fees, costs of suit and such other relief the court deems equitable and just.

PUNITIVE DAMAGES ALLEGATIONS

(AGAINST ALL DEFENDANTS)

145. Plaintiffs incorporate by reference and hereby reallege paragraphs 1 through 144 as though fully set forth here and further allege as follows:

146. The acts, conduct, and omissions of Defendants, and each of them, were willful and malicious and were done with a conscious disregard for the rights of Plaintiffs and other foreseeable users of the pharmaceutical agents mentioned herein, and for the primary purpose of increasing Defendants' and each of their, profits from the sale and distribution of their drug products. The outrageous and unconscionable conduct of Defendants, and each of them, as set forth herein, warrants an award of exemplary and punitive damages against Defendants, and each of them, in an amount appropriate to punish and make an example of each defendant.

147. Prior to the manufacturing, sale and distribution of the aforesaid pharmaceutical drug products Defendants, and each of them, knew that said pharmaceutical drug products were in a defective condition as previously described herein and knew that those who were prescribed and the foreseeable users who took them would experience and did experience severe and permanent physical, mental, and emotional and economic injuries. Further, Defendants, and each of them, through their officers, directors, managers and agents, had knowledge that their drugs used either singly or in combination in a foreseeable manner, presented a substantial and unreasonable risk of harm to the public, including Plaintiffs and as such, said purchasers and/or consumers of said drugs were unreasonably subjected to risk of permanent injury from the consumption of said drugs.

148. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing their profits, knowingly and deliberately failed to remedy the known defects in said drugs and failed to warn any and all persons who prescribed, purchased or consumed Defendants' products, including but not limited to, any and all physicians and foreseeable users of the products, of the extreme and permanent risks associated with the foreseeable uses of their drugs and their defective nature. Said Defendants, and each of them, as well as their individual agents, officers, and directors

intentionally proceeded with the manufacturing, packaging, labeling, distribution, marketing and sale of said drugs knowing that foreseeable users would be exposed to serious potential danger in order to advance Defendants' and each of their, own pecuniary interest and monetary profits. The conduct of Defendants, and each of them, was despicable, and so contemptuous that it would be looked down upon and despised by ordinary decent people, and carried on by Defendants, and each of them, with willful and conscious disregard for the safety of Plaintiffs entitling Plaintiffs to exemplary damages under *California Civil Code* Section 3294.

DEMAND FOR JURY TRIAL

The Plaintiffs STEPHEN WENDELL AND LISA WENDELL, his wife, for themselves and as successors-in-interest to MAXX WENDELL, demand a trial by jury on all issues so triable in this civil action.

DATED: February 9, 2010

BY: */s/ Fabrice Vincent*

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